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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re patent application of: :
EDWARD L. TOBINICK, M.D.

Serial No. : Group Art Unit

Filed: December 26, 2000 : Examiner

For: CYTOKINE ANTAGONISTS FOR THE TREATMENT OF SENSORINEURAL HEARING LOSS :

Assistant Commissioner for Patents
Washington, D.C. 20231

PETITION TO MAKE SPECIAL
(MPEP Section 708.02)

Sir:

Applicant hereby files this Petition to Make Special this application for the purposes of examination and payment of the issue fee, on the grounds of a pre-examination search. Applicant also submits the petition fee.

The application presents claims directed to a single invention. In case the Examiner believes that there is more than one invention, applicant hereby elects without traverse Claims 1 to 15.

A pre-examination search was made of the records of the U.S. Patent Office by applicant's attorney, Ezra Sutton. The field of search included Class 514, Subclasses 2, 12, 171, 261, 262, 264, 282, 323, 327, and 348; Class 530, Subclasses 324, 350, and 399;

Class 424, Subclasses 158.1 and 810; and Class 435, Subclasses 69.1, 69.52, 69.7, 91.41, and 240.27.

INVENTION SEARCHED

Specific Cytokine Antagonists, including TNF antagonists and/or Interleukin-1 antagonists, are used as novel therapeutic agents for the treatment of hearing loss, including presbycusis and other forms of sensorineural hearing loss. The present invention provides a method for inhibiting the action of TNF and/or IL-1 antagonists for treating hearing loss in a human by administering a TNF antagonist and/or an IL-1 antagonist for reducing the inflammation affecting the auditory apparatus of said human, or for modulating the immune response affecting the auditory apparatus of said human, by administering a therapeutically effective dosage level to said human of a TNF antagonist and/or an IL-1 antagonist. Administration may be systemic, through the subcutaneous, intramuscular, oral, or intravenous routes; or by delivering an anatomically localized application in the region of the head. The TNF antagonist is selected from the group consisting of etanercept, infliximab, D2E7, CDP 571, or thalidomide; and the IL-1 antagonist is either IL-1 RA or IL-1R type II receptor. Antiviral agents may be added for treating certain patients.

PATENTS SELECTED IN SEARCH

As a result of the search, we have uncovered the following U.S. patents:

U.S. Patent No.	Inventor	Issue Date
5,075,222	Hannum et al	Dec. 24, 1991
5,385,901	Gilla et al	Jan. 31, 1995
5,434,170	Andrulis	July 18, 1995
5,559,114	Exley	Sept. 24, 1996
5,605,690	Jacobs et al	Feb. 25, 1997
5,656,272	Le et al	Aug. 12, 1997
5,837,681	Magal	Nov. 17, 1998
5,863,769	Young	Jan. 26, 1999
6,043,221	Magal et al	Mar. 28, 2000
6,124,322	Bjoerkman	Sept. 26, 2000

A copy of each patent is enclosed.

DISCUSSION OF SELECTED PATENTS

U.S. Patent No. 5,837,681 is entitled "Method For Treating Sensorineural Hearing Loss Using Glial Cell Line-Derived Neurotrophic Factor (GDNF) Protein Product". However, this prior art patent does not teach the use of a TNF antagonist or interleukin-1 antagonist for the suppression and inhibition of the action of TNF and/or interleukin-1 in the human body to treat hearing loss, as in the present invention.

U.S. Patent No. 6,043,221 entitled "Method For Preventing And Treating Hearing Loss Using A Neuturin Protein Product" discusses the use of a neurotrophic factor. This prior art patent does not teach the use of a TNF antagonist or interleukin-1 antagonist for

the suppression and inhibition of the action of TNF and/or interleukin-1 in the human body to treat hearing loss, as in the present invention.

U.S. Patent No. 5,385,901 entitled "Method Of Treating Abnormal Concentrations of TNF Alpha" discloses a method for the use of TNF antagonists. This prior art patent does not teach the use of a TNF antagonist or interleukin-1 antagonist for the suppression and inhibition of the action of TNF and/or interleukin-1 in the human body to treat hearing loss, as in the present invention.

U.S. Patent No. 5,434,170 entitled "Method For Treating Neurocognitive Disorders" discloses the use of thalidomide to treat dementia. This prior art patent does not teach the use of a TNF antagonist or interleukin-1 antagonist for the suppression and inhibition of the action of TNF and/or interleukin-1 in the human body to treat hearing loss, as in the present invention.

U.S. Patent No. 6,124,322 entitled "Intravenous Form Of Thalidomide For Treating Immunological Diseases" discloses a new aqueous form of thalidomide. This prior art patent does not teach the use of a TNF antagonist or interleukin-1 antagonist for the suppression and inhibition of the action of TNF and/or interleukin-1 in the human body to treat hearing loss as in the present invention.

U.S. Patent No. 5,863,769 discloses the DNA sequence encoding IL-1 RA, and its use for treating various diseases. This prior art patent does not teach the use of an interleukin-1 antagonist for

the suppression and inhibition of the action of interleukin-1 in the human body to treat hearing loss as in the present invention.

U.S. Patent No. 5,075,222 discloses the DNA sequences encoding IL-1 inhibitors. This prior art patent does not teach the use of an interleukin-1 antagonist for the suppression and inhibition of the action of interleukin-1 in the human body to treat hearing loss, as in the present invention.

U.S. Patent No. 5,605,690 discloses a method for treating TNF-dependent inflammatory diseases, such as arthritis, by administering a TNF antagonist, such as soluble human TNFR (a sequence of amino acids), to a human. This prior art patent does not teach the use of a TNF antagonist or interleukin-1 antagonist for the suppression and inhibition of the action of TNF and/or interleukin-1 in the human body to treat hearing loss, as in the present invention.

U.S. Patent No. 5,656,272 discloses methods of treating TNF-alpha-mediated Crohn's disease using chimeric anti-TNF antibodies. This prior art patent does not teach the use of a TNF antagonist or interleukin-1 antagonist for the suppression and inhibition of the action of TNF and/or interleukin-1 in the human body to treat hearing loss, as in the present invention.

U.S. Patent No. 5,559,114 discloses the use of acyclovir and famciclovir at higher than normal doses to treat autoimmune disease. This prior art patent does not teach the use of antiviral drugs combined with a cytokine antagonist in the human body to treat hearing loss, as in the present invention.

CONCLUSION

The compositions and methods of these prior art patents do not disclose or teach the claimed method of the present invention of using a TNF antagonist or an IL-1 antagonist for the suppression and inhibition of the action of TNF and/or IL-1 in the human body to treat hearing loss, as in the present invention.

The distinctions over the prior art are set forth in the claims, and they patentably distinguish over the prior art. Accordingly, this Petition should be granted.

Respectfully submitted,

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Enclosures